VA - New Mexico VA Health Care System (NMVAHCS)
D16-00040 (A3073-01)

Animal Welfare Assurance for Domestic Institutions

I, (b)(6) as named Institutional Official (IO) for animal care and use at New Mexico VA Health Care System, hereinafter referred to as Institution, provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

I. Applicability of Assurance

This Assurance applies whenever the Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS, DHHS, and/or NSF (if applicable). This Assurance covers only those facilities and components listed below.

A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name: Veterinary Medical Unit (VMU)

B. The following are other institution(s), or branches and components of another institution: Biomedical Research Institute of New Mexico (BRINM)

Note: only those entities listed in this section will be entitled to use the Assurance number for grant and contract submissions to PHS agencies.

II. Institutional Commitment

A. This Institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.

B. This Institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."

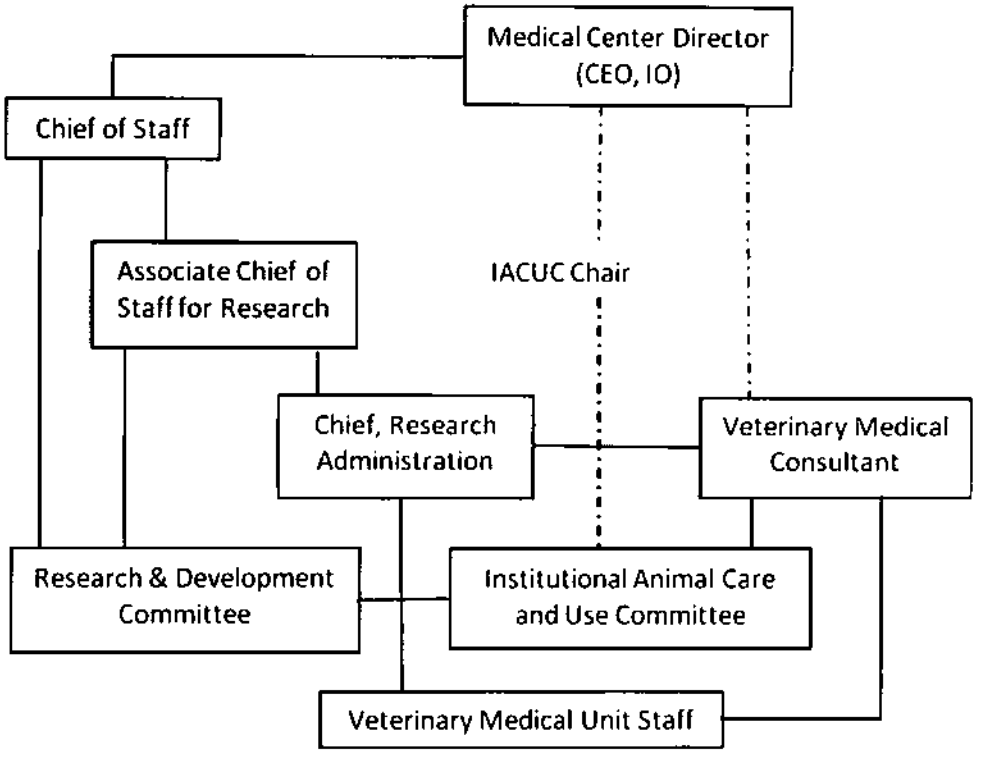
C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, and other applicable laws and regulations pertaining to animal care and use.

D. This Institution has established and will maintain a program for activities involving animals according to the *Guide for the Care and Use of Laboratory Animals* (*Guide*).

E. This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (sub award) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval.

III. Institutional Program for Animal Care and Use

A. The lines of authority and responsibility for administering the program and ensuring compliance with the PHS Policy are as follows:



B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:

1) Name (b)(6)
Qualifications:
- Degrees: D.V.M., DACLAM
- Training or experience in laboratory animal medicine or in the use of the species at the institution (b)(6) graduated from the College of Veterinary Medicine, (b)(6) (b)(6) with a DVM. While in the (b)(6) he attended a 4 year Laboratory Animal Medicine Residency at (b)(6) He completed this program and was board certified by the American College of Laboratory Animal Medicine (ACLAM) in (b)(6) He has been engaged full time as a laboratory animal veterinarian since (b)(6) He regularly reviews journals and literature

and attends AALAS meetings, ACLAM forums, and other conferences related to laboratory animal care and use.

Authority: (b)(6) has **direct** program authority and responsibility for the Institution's animal care and use program including access to all animals.

Time contributed to program: (b)(6) contracted to spend 10% of his time contributing to our program. He makes weekly visits to inspect animal and facility conditions. He provides programmatic support by review of IACUC protocols (ACORPS), operational procedures, and other Animal Care and Use Program documents on site and remotely. When not on station, he is available on-call for emergencies and the VMU supervisor and Research faculty and staff consult him regularly.

During the time that (b)(6) s not on station (b)(6) is responsible for daily animal care and facility management. It is her responsibility to contact (b)(6) f a problem arises that she cannot resolve. If the problem cannot be resolved by phone or electronic consultation with (b)(6) comes on site to resolve the problem.

When (b)(6) s unavailable, in order to ensure adequate veterinary care, emergency veterinary services are provided through an arrangement with the veterinarian at of the Rio Grande Zoo, Albuquerque BioPark. They will always be accompanied by one of the VMU staff if they are called to campus.

Qualifications: The veterinarian has extensive animal care and clinical competency with a number of exotic species including those species held at the NMVAHCS.
Names:

(b)(6) **, D.V.M.**, completed her veterinary degree in (b)(6) at the (b)(6) University and worked in an exotic animal practice for three years prior to completing a two year residency in Zoo Animal Practice at the (b)(6) Sinc (b)(6) she has practiced zoo animal medicine and is currently the head veterinarian at the (b)(6) (b)(6) and she is responsible to provide the clinical care for a wide variety of species. In 2012, she completed Board Certification in the American College of Zoological Medicine. She is a very competent clinician with 15 years' experience caring for a wide variety of species including the laboratory rodent and rabbit species housed at the Albuquerque VA Veterinary Medical Unit.

C. The IACUC at this Institution is properly appointed according to PHS Policy IV.A.3.a. and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least 5 members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. Attached is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations.

D. The IACUC will:

1) Review at least once every 6 months the Institution's program for humane care and use of animals, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:

The IACUC conducts the semiannual review at least every 6 months, using the *Guide*, and the VA Semiannual Evaluation of the Institutional Animal Care and Use Program and Facilities Form. Each member is encouraged to participate in semiannual facility inspections, and the Program Review. No IACUC member wishing to participate in semiannual facility inspections and/or the program review is prevented from doing so. This review of institutional policies and responsibilities include: IACUC membership and functions, protocol review process, animal facility inspection process, provisions for reviewing and investigating concerns regarding animal care and use, IACUC record and reporting requirements, veterinary care

program, personnel, emergency preparedness, post-approval monitoring, security, and other aspects of the program, according to Chapter one of the Guide. The program of veterinary medical care is evaluated to determine what is intended or expected from institutional policies, transportation procedures, surgery guidelines, pain, distress, analgesia, and anesthesia guidelines, euthanasia guidelines (AVMA Guidelines on Euthanasia), and drug storage and control. The program review is completed every six months along with the facility inspection.

2) Inspect at least once every 6 months the Institution's animal facility, including satellite facilities animal surgical sites, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:

The IACUC inspects the animal facility every six months using the Guide as a basis for evaluation. IACUC procedures for semiannual facility inspections are as follows: At least three members of the IACUC physically inspect the VMU, noting any deficiencies or departures from the provisions of the Guide. This information is used when filling out the VA Semiannual Evaluation of the Institutional Animal Care and Use Program and Facilities Form, a checklist utilized when the IACUC conducts the semiannual facility inspections. This checklist is based on the examples of checklists found on the OLAW website, but is more extensive. This checklist covers:

a. All rooms and laboratories in which animals are housed or used > 12 hours,

b. Specialized spaces such as surgery, and support facilities such as storage, locker rooms, and cage wash areas,

c. All laboratories where survival and non-survival surgery and other procedures are performed.

3) Prepare reports of the IACUC evaluations according to PHS Policy IV.B.3. and submit the reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows:

a. The VA Semiannual Evaluation of the Institutional Animal Care and Use Program and Facilities Forms consist of three forms: Form 1. Checklist categorizing deficiencies as major or minor; Form 2. Table of Program and Facilities Deficiencies that lists the location of, description of, reason(s) for, plan and a timetable for correction of, any deficiencies. This form is used to track subsequent corrective actions; Form 3. Post-Review Documentation that lists members of the review team, minority opinion(s), and review and approval by IACUC members (signatures). These forms are discussed at the next convened IACUC meeting.

IACUC-approved departures from the PHS Policy and the *Guide* are included in the semiannual report, with the reasons for each.

b. After a majority of all voting IACUC members approve/sign the report, the Veterinary Medical Consultant, IACUC Chair, and the Associate Chief of Staff for Research and Development (ACOS/R) discuss the report with the Medical Center Director (IO). Other IACUC members may also attend. The IO must sign the report indicating that he/she has reviewed it. A signed copy of the complete report (including Forms 1, 2, 3) is sent through the ACOS/R and IO to the VA Chief Veterinary Medical Officer (CVMO) within 60 days of the self-assessment date. The Research and Development Committee (R&DC) reviews the approved report as an item of business, but R&DC approval is not required before submission of the final document to the CVMO. The original document must be retained for at least three years.

4) Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:

The VA is obligated to provide a mechanism for individuals to report concerns about animal welfare and compliance with the Animal Welfare Act regulations (9 CFR Chapter 1, subchapter A), the U.S. Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy), the Guide for the Care and Use of Laboratory Animals published by the National Academy of Science (Guide), all protocols approved by the IACUC, and IACUC policy and procedure. Employees are encouraged to report any concerns immediately. Signs are posted in the animal facility listing the phone numbers of the IACUC chairperson, the Veterinary Medical Consultant (VMC), the animal facility supervisor, and the research compliance officer. Concerns are corrected at the lowest possible level by reporting them first to the VMC through the VMU Supervisor on an informal basis. If a satisfactory response is not received, the concern is taken to the IACUC. Concerns reported to the IACUC are forwarded to the Chair of the IACUC promptly. The Chair of the IACUC (with consultation from the VMC or other members of the IACUC when appropriate) has the authority to initiate an investigation.

Procedures the IACUC uses to review reported concerns: The concern will be evaluated relative to the applicable provisions of the Animal Welfare Act and Animal Welfare Regulations (AWAR), the Guide, the Institutional Assurance, VHA Handbooks 1200.07 and 1058.01, and IV.C.1a-g of PHS Policy (Published Standards). Concerns raised will be discussed at the regularly scheduled meetings unless meeting specific criteria to warrant holding a special meeting. Seriousness of concern and need for a special meeting will be decided by the IACUC Chairperson.

If the investigation concludes that animal care and/or use is appropriate or no violation of published standards has occurred, no further investigative or corrective action will be taken.

Any event that results in suspension or termination of approved animal research must be reported directly by the IACUC Chair to the IO within 5 business days and in writing. The IO will report the suspension/termination to the CVMO and The Office of Research Oversight (ORO) within 5 business days. The IACUC must also provide a copy of the report to OLAW, AAALAC, USDA (if a covered species), and the sponsor and funding source of any affected projects.

Under federal regulations, no employee or IACUC member shall be discriminated against or be subject to retaliation in any form for reporting, in good faith, a concern about animal care or use or cooperation with an IACUC investigation. Persons making fraudulent allegations ill be subject to disciplinary action, up to and including termination or expulsion. The IACUC chair shall communicate, in writing, a summary of the complaint and assurance that an investigation will be conducted in compliance with the policies and regulations of the institution.

5) Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows:

Written recommendations are included as part of the semiannual report to the IO. Other recommendations are sent in writing (as part of the IACUC minutes) to the R&DC. The R&DC will, in turn, act appropriately, note this action in the R&DC's minutes, and forward them to the IO for final approval. However, the IACUC may at any time provide a recommendation if a significant deficiency is noted. If any IACUC committee member expresses a concern regarding the program or facilities, it will be discussed at the next convened meeting. If an immediate concern arises, any member of the IACUC or staff may discuss the concerns with the ACOS/R and IO.

6) Review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals according to PHS Policy IV.C.1-3. The IACUC procedures for protocol review are as follows:

New Protocols:

The Principal Investigator (PI) sends a completed electronic copy of the Animal Component of Research Protocol (ACORP) to the Veterinary Medical Consultant for pre-review and comments. The PI finalizes the ACORP and submits it electronically to the Research Office. All protocols, regardless of funding source (including pilot and internally funded studies) are submitted through electronic submission. The ACORP is then sent electronically to all IACUC members along with the meeting agenda.

A quorum of the IACUC must be present before conduct of business under full committee review (FCR). The committee may invite the PI to attend a convened meeting to summarize or answer questions about the protocol. Once all questions are answered, the PI leaves the room while the IACUC members discuss and vote on motions associated with the protocol. Approval of a motion requires affirmative vote of the majority of the quorum present. No member may participate in the IACUC review or approval of a research project in which the member has a conflicting interest, except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum. The IACUC may invite consultants to assist in the review of complex issues. Consultants may not approve or withhold approval of an activity or vote with the IACUC unless they are also members of the IACUC.

Following discussion at the convened meeting, possible committee decisions include:

Approval: The protocol is approved as written. However, the R&D Committee or IO may disapprove a project that the IACUC has approved.

Withhold approval: The IACUC shall include in its electronic notification a statement of the reasons for its decision and give the PI an opportunity to respond in person or in writing. The R&DC or IO may not overturn this decision.

Require modifications to secure approval: When substantive information is lacking from a protocol, the committee may decide to return it to the PI for clarifications.. The committee may decide that the revised protocol must be reviewed in a convened meeting or by unanimous decision to have the revised research protocol reviewed and approved by designated member review (DMR). When multiple reviewers are assigned for DMR, all decisions must be unanimous. In this case, if not unanimous, then the protocol must return to a convened meeting for action. Currently all members of the IACUC have signed approval of this DMR process (described below) following a convened meeting in compliance with OLAW guidance.

Tabling the protocol:

The PI is informed of the outcome of the protocol review process electronically from the IACUC following the convened meeting.

All existing protocols must be resubmitted a complete *de novo* IACUC review as described for new protocols every three years, regardless of funding source. The PI is notified electronically in advance of the upcoming 3-year expiration date of the protocol. The submission must include an entirely re-written protocol with a progress report of the previous three years and a literature review. At the end of the 3 year approval, all vertebrate research under the protocol/project must cease if the replacement protocol is not approved.

All protocols require a search for alternatives. Protocols that have a potential to cause significant pain or distress are reviewed in the same manner as all protocols. However, these protocols require additional information including justification, description of humane endpoints, and monitoring procedures that must be provided by the PI at the time of submission. Whenever indicated, the VMC consults with the PI to formulate an animal health monitoring sheet specific for the protocol. The protocol-specific animal monitoring/scoring sheet is maintained in the animal room for the PI and/or VMU staff to use when checking

these animals during daily rounds. Each monitoring sheet is formulated based upon the experimental risks with anticipated signs, and a relative scoring index to assist in determining humane endpoints.

The Designated Member Review Process:
If a submission is received and is a candidate for DMR, Research Administration initiates the process as follows:

- Distribute the protocol to the full Committee via e-mail.
- Give each Committee member five calendar days to review the proposal and request full committee review of the submission. The members can recommend approval of the DMR process but an affirmative response is not mandatory. Any voting committee member may request a full convened meeting.
- If any member requests review at a convened meeting then DMR will not be authorized.
- If no committee member requests a full committee review the DMR process can commence after the 5 calendar day waiting period.
- The IACUC Chair then appoints the Designated Member(s) who will conduct the review.
- Research Administration will provide the conduit for communication between the PI and the DMR subcommittee, electronically.
- If more than one member is assigned to the DMR then all decisions must be unanimous. If a unanimous decision cannot be made then the protocol must be reviewed during a full convened meeting with a quorum present.
- Possible DMR decisions:
    - Approve the protocol, amendment, or annual review submission.
    - Request information/modifications in order to secure approval.
    - Defer the submission to full committee for review in a convened meeting if a unanimous decision cannot be made or if any member of the DMR requests full committee review.
- The DMR subcommittee cannot disapprove a protocol.
- The protocol approval date is the date that the designated member(s) approve the study.

7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities according to PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:

Proposed changes to an approved ACORP may be submitted to the IACUC as an amendment if there is a definite and clear link to the hypothesis presented in the original protocol and if the proposed change(s) are easily interpretable as a change or outgrowth of the original protocol.

The IACUC requires that all changes (Minor or Major amendments) to an approved protocol be submitted electronically to the Research Office. The VMC and the IACUC Chair have been designated by the VA IACUC to determine if proposed modifications represent minor or major changes to the existing protocol. Decisions are based upon PHS policy, OLAW guidance and VHA Handbook 1200.07.

Minor Amendments:
The VMC and the IACUC Chair review and administratively approve minor modifications to existing protocols. The reviewers can request additional information in order to secure approval or, if acceptable, they can approve. Minor amendments for a change in personnel are reviewed and approved administratively by the IACUC Chair following confirmation that all training and occupational health requirements have been met.

The minor amendment is listed on the agenda at the next convened meeting. If any IACUC member requests further review of minor modifications, a review will be conducted at the next meeting.

Major Amendments (significant modifications): These modifications are processed and reviewed the same as original protocols (i.e. requiring approval either through designated member review or review during a convened committee meeting with a quorum).

Veterinary Review (VR):
The following changes are NOT acceptable for VR:

- change procedures from non-survival to survival surgery;
- result in greater potential pain, distress, or degree of invasiveness;
- add/alter procedural/housing location(s) that have not been previously approved by the IACUC for the described purpose(s);
- change species, study objectives, Principal Investigator, or personnel safety; and
- addition of new procedure types that were not previously approved under the protocol (e.g. surgery, blood collection, administration of similar class of agent, etc.).

The following specific changes described below may be handled administratively without full committee review (FCR) or designated member review (DMR) via VR as authorized in advance by the IACUC. Changes in:

- Anesthesia, analgesia, sedation, or experimental substances.
- Euthanasia by any method approved in the AVMA Guidelines for the Euthanasia of Animals; and
- Duration, frequency, type, or number of previously approved procedure types performed on an animal.

The VR process is based upon IACUC approved policies, the veterinarian's professional judgement, relevant peer reviewed literature (when applicable), and the following approved reference resources:

Hawk and Leary's Formulary for Laboratory Animals; Flecknell's Laboratory Animal Anesthesia; Plumb's Veterinary Drug Handbook; Harkness and Wagner's Biology and Medicine of Rabbits and Rodents; and AVMA Guidelines for the Euthanasia of Animals.
The IACUC has authorized the Veterinary Medical Consultant to verify the significant changes according to IACUC policies. These changes are documented on an amendment form and a letter of approval from the IACUC.

8) Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval according to PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

   The Institution is notified in writing through the minutes of the IACUC, which go through the R&D Committee and then to the IO. Semi-annual Program and Facility Inspections Reports of significant deficiencies and suspensions are sent directly to the IO.

   All notifications are sent electronically. When a decision on a submission has been made at a convened meeting, the decision is recorded in the meeting minutes. When an approval is granted an approval letter is generated. The letter is sent electronically to the PI, the Veterinary Medical Unit personnel, and an electronic copy is maintained by the Research Office.

   If the IACUC decides to withhold approval, or requires modifications to secure approval, then the memo includes the reasons for the IACUC decision and states any required modifications. The PI may respond in writing to this memo.

9) Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review at

least once every 3 years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:

Post Approval Monitoring (PAM): Ongoing activities are monitored through a PAM program. A Post-Approval Monitoring Audit Sheet is used by the IACUC Chair, VMU supervisor, and other IACUC members to randomly query those performing live vertebrate animal work within the VMU. During this audit, the reviewer asks questions that are detailed in the approved protocol to determine whether activities are compliant. Training status and enrollment in the Occupational Health Program (OHSP) are also verified.

Prior to the 3-year expiration of each approved ACORP, the IACUC Chair, or designee , will set up a meeting with the PI to go over, and fill out an IACUC Post-Approval Monitoring (PAM) Checklist. This is a more formal process than the audit sheet and involves reviewing the ACORP as a whole.

The results of the PAM are sent to the PI for review and corrective action. If deficiencies are found, a PAM meeting will be scheduled with the PI within six (6) months. The results and corrective actions will be reviewed by the IACUC at the next convened meeting.

Triennial Review: PIs must submit a new protocol for *de novo* review with an approval prior to the end of the three year anniversary date for work on a project to continue. The Research Office notifies every PI of impending expiration of a protocol at 90 days, 60 days, and 30 days prior to expiration of their protocol(s). Failure to renew an expired protocol results in a halt in animal ordering and research, and is enforced by the Veterinary Medical Unit under the authority of the IACUC. No animal work may be conducted past the protocol's date of expiration (3 years from approval). This review is completed by either FCR or DMR procedures (as in Section III.D.6).

Annual Review:
After initial approval of an ACORP, annual review will be required. Ongoing reviews are considered compliant if they are completed within the same month as the anniversary date of the most recent previous approval. It is also acceptable for the review to be carried out up to 5 weeks before the anniversary date, with the approval effective on the anniversary date. Prior to the annual anniversary date, electronic reminders will be sent to the PI by Research Service Administration personnel. A repeat electronic reminder will be sent if there is no action by the PI.

The PI completes an "Annual Review of Animal Use" form which asks about project status including: if animal use has been in accord with the approved protocol, if changes in animal work are anticipated, if there are any hazards involved with the project, changes to personnel, and verification of the number of animals used during the year. The PI submits it electronically to the Research Office. Annual review forms will be reviewed by the IACUC Chair, following the DMR process, for the number of animals used by stress category, use of biohazards, and training status of all study personnel. The IACUC Chair will also verify that protocols using biohazards have an approved Research Protocol Safety Survey (RPSS) at the time of annual review.

The Annual renewal/review is approved when all questions and/or comments have been answered in a satisfactory manner. All annual reviews are placed on the agenda of the next convened full Committee meeting. Each member has full access to the protocols and they can request FCR of any protocol of concern.

10) Be authorized to suspend an activity involving animals according to PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows:

The IO may suspend animal protocols for any reason. The IACUC may suspend an activity after review of the matter following a majority vote at a convened meeting with a quorum present.

All members of the VA research community are obligated to report (in writing or anonymously) to the IACUC within five (5) business days of any unexpected outcome or event that results in impaired animal health or welfare, injury or safety concerns for research staff, or operational problems that necessitate an interruption in the conduct of animal research. The IACUC will evaluate all reported concerns and notify the PI lab, the individual making the report, if known, and the Institution if concerns were substantiated.

The IACUC Chair is responsible for appointing an investigative subcommittee to collect information, interview personnel, and report back to the IACUC. The Chair will communicate the IACUC's intent to convene an investigative subcommittee to the IO, Research Compliance Officer (RCO), and ACOS/R. If an incident is considered serious, the IACUC Chair will promptly notify the CVMO, ORO, and OLAW that an incident is under investigation.

When necessary, the IACUC chair will promptly convene an "emergency" meeting of the IACUC. The IACUC, will review the investigative subcommittee's report to determine by majority vote (with a quorum) whether the reported activity represents significant or continuing non-compliance or a serious deviation from the *Guide*, in which case a suspension may be decided by a majority vote of the quorum present at the meeting.

Whether or not the protocol is suspended, the IACUC shall decide what corrective action(s) must be implemented. The PI will be notified of the final decision which may include suspension of all animal activities and a corrective action plan. The PI has the right to appeal this decision within 2 weeks and request a meeting with the IACUC.

Once corrective actions have been completed, and are acceptable to the IACUC, if the protocol was suspended, it can be reactivated following a majority vote of the IACUC.

E. The risk-based occupational health and safety program for personnel working in laboratory animal facilities and personnel who have frequent contact with animals is as follows:

The New Mexico VA Health Care System occupational health and safety program (OHSP) includes a comprehensive program for all individuals that have animal contact in association with Institutional sponsored activities. The requirements of the program are based upon the National Research Council (NRC) guidelines: Occupational Health and Safety in the Care and Use of Research Animals (1997) and the Center for Disease Control and Prevention/National Institute of Health (CDC/NIH) guidelines, Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition or current. The OHSP's goal is to prevent occupational injury and illness. The program consists of:

- Risk Assessment - defining and quantifying hazards
- Safety Program - avoiding and controlling hazards and exposures
- Training and Education - risk assessment communication
- Rules and Guidelines - safe work practices and procedures
- Medical Monitoring - health assessment program
- Recordkeeping - monitor safety programs and identify deficiencies

<u>Hazard identification and risk assessment</u>:

The Subcommittee on Research Safety, Biosafety, and Security (SRSBS) is responsible for monitoring all research biosafety activities, including risk assessment of biohazardous agents and the identification of chemical and physical hazards at NMVAHCS. The Institutional Biosafety Committee (IBC) is responsible for monitoring work with recombinant DNA. The Employee Health Service operates the OHSP and the employee health physician provides guidance to Research Service in developing and maintaining this program. The SRSBS includes the Industrial Hygiene Officer (IH) who is responsible for monitoring and oversight of chemical hazardous agents. Researchers are responsible for notifying the SRSBS if any hazardous agents are to be used in the conduct of research. The IH advises researchers of the necessary safeguards and policies

regarding hazardous agents. Chemical hazard risks are determined by reviewing the Safety Data Sheet (SDS), experimental protocol, and specific agent. Biological hazard risks are evaluated according to the CDC/NIH BMBL and the NIH Guidelines for Recombinant DNA. Approval to use Biohazardous agents must be approved by the SRSBS. The Radiation Safety Official evaluates radiation hazards for each isotope, procedure, etc. on a scenario-specific basis. Guidelines published by the National and International Committees on Radiation Protection (ICRP and NCRP) are consulted. For all hazardous agents, the NRC Occupational Health and Safety in the Care and Use of Research Animals is further consulted. Animal-related risks are evaluated by the VMC and the SRSBS during IACUC protocol review and project review respectively. The Research Safety Coordinator (RSC) conducts visits to laboratories and facilities, where hazardous agents may be present, to determine compliance with institutional, city, state, and federal regulations.

Facilities, equipment, and monitoring:

The VMU has facilities for Biosafety Level 2 infectious agents. The ABSL 2 animal rooms are located on the (b)(6) here are three 240 square foot animal housing rooms. One autoclave is provided for sterilizing infectious waste. All infectious agent work with rodents is conducted within a Biological Safety Cabinet. All potentially infectious cages, water bottles, and wastes are autoclaved out. Bedding from these areas is autoclaved in the cages, dumped in red bags/red barrels and then disposed of as infectious waste. The infectious waste from this area is "red-bagged" and further handled (in addition to autoclaving) as regulated medical waste, that is stored in sealed containers in a secure, safe area until processed off-site by a licensed medical waste disposal contractor. Entrances are properly labeled with the universal biohazard symbol, the infectious agents in use, the name and telephone number of the responsible PI for each agent, the emergency number for after hours contact, and special requirements for entering the rooms. Access is restricted to those properly trained and authorized to be in this area. Each room is supplied with 100% fresh / 100% exhausted air. Walls and ceilings are concrete block and epoxy painted to an impervious surface. Floors are epoxy aggregate surface over a concrete base with a cove providing a seamless, smooth, impervious floor.

Personnel training regarding zoonoses, chemical safety, physical hazards, allergies, handling of waste materials, precautions taken during pregnancy, illness or immune suppression:
Individuals covered by the program include any person who has direct exposure to vertebrate animals, animal tissues, body fluids or wastes. Enrollment in Occupational Health and Safety educational programs is mandatory for all personnel involved in animal contact. Additional training for handling hazardous materials is provided by the SRSBS, investigator's staff, the VMU professional staff, or others with expertise in the field. Individuals involved in isolated one-time contact shall be informed of specific health precautions and appropriate vaccinations or medical constraints. Isolated one-time contact will not require participation in the medical monitoring program.

Personal Training for Specific Procedures:
All projects involving the use of hazardous agents in animals are reviewed by the IACUC as part of the standard review process. An SOP for VMU personnel must be completed prior to initiation of any animal studies involving hazards. The IACUC requires that projects be reviewed and approved by the appropriate committee according to the proposed agent. The SRSBS and/or RSC provide training in radiation safety, chemical safety, work safety, etc. for personnel with potential contact with hazardous substances. The IH provides training on respirator use and conducts annual fit tests for N95 respirators, when applicable. The PI is responsible for assuring that all personnel are adequately trained. The PI must submit a standard operating procedure, precautions, occupational health concerns and monitoring requirements, and any additional training requirements for the care of the animals to the VMU. The VMU staff monitors all aspects of using hazardous agents in laboratory animals in the VMU. SRSBS and/or IBC officials provide additional monitoring, training, and consultation if needed. The VMU staff is trained to handle the hazardous materials in research animals on current protocols. Additional training will be provided as required for each new agent.

Personal hygiene:

Sinks, soap and paper towels are available in animal rooms, laboratories, procedure rooms, lavatories, and the employee lounge for washing hands. Personnel are required to wash hands upon exiting animal rooms. Showers, lockers, and changing facilities are available for animal care personnel in the VMU. At a minimum, the animal care technicians change uniforms daily. Work uniforms are restricted to use only in the VMU. The animal care staff may leave the VMU to go outside, to the canteen, etc., if they wear a clean lab coat or similar covering over their uniforms. If they leave the NMVAHCS campus, they must change into their personal clothing. Clean uniforms consisting of scrubs are furnished to all VMU animal care personnel on a daily basis. The uniforms are provided by the VMU and laundered by the institution. Shoes are also provided for the VMU animal care personnel. Lab coats, respirators, disposable protective smocks, gloves, masks, caps, and shoe covers are also provided for work with hazardous agents as required.

Animal experimentation involving hazards:
The PI is required to identify hazards associated with his/her research protocol and enforce the appropriate safeguards for those working in the project, based upon recommendations from the SRSBS and IBC. All work with hazardous agents must be cleared through the SRSBS. Evaluation of animal specific hazards, protocol hazards, and potential for exposure to hazardous agents is conducted jointly by the PI, VMC, animal care personnel, SRSBS, and IBC. An approved copy of the RPSS, with the signature of the Safety Officer, needs to be on file in the Research Office. The IH, Radiation Safety Officer, SRSBS and IBC provide information, monitoring, and assistance, as needed, for any work involving hazardous biological, chemical, and physical agents. The occupational health program is tailored by Employee Health accordingly for personnel potentially exposed to hazardous agents. This is evaluated on a case-by-case basis and may include more frequent physical examinations and/or more inclusive clinical pathology work-ups as it relates to the hazardous agent.

The IACUC reviews all protocols, including those involving the use of hazardous agents. The project PI must submit an SOP for handling potentially hazardous animals, and a safety plan to the SRSBS and the IACUC that describes the hazardous agents to be used and the safety precautions to be followed by the animal care personnel. The VMC and/or VMU supervisor reviews these precautions with the VMU techs, and these are posted as an SOP in the animal facility. The SRSBS and VMU staff jointly monitors the program.

The VMU and all laboratories at the NMVAHCS are inspected as needed by the hospital Environment of Care Committee and Veterans Integrated Service Network (VISN) Industrial Hygienist. The inspections involve evaluation of:

- Fire Safety
- Electrical/Mechanical Safety
- Storage and Housekeeping
- Compressed Gases
- Chemical and Laboratory Safety

The VA Radiation Safety Committee establishes policies and rules for radiation control and safety, and reviews proposals for the use of sources of ionizing radiation. The Radiation Safety Officer oversees the collection, use, transportation, and disposal of radioactive materials. There are currently no animal protocols approved for radioactive use.

The VA SRSBS reviews research protocols involving biohazardous agents (excluding recombinant DNA) and associated biological safety. The VA IBC reviews research protocols involving recombinant DNA.

Personal protective equipment is provided by employer-based upon risk assessments and recommendations by SRSBS and/or IBC. Currently available equipment includes N95 respirators, goggles, safety glasses, face shields, gowns, gloves, masks, boots or shoe covers.

Biohazardous Agents:
The animals exposed to Biohazards are housed in the (b)(6) rooms. The entrance to these suites is restricted and properly labeled. The VMU staff is responsible for all animal care and maintenance of the animal housing and follows CDC/NIH guidelines: BMBL

and the Guide. Special procedures and precautions, safety plans, and a SOP for animal care for animals exposed to potentially hazardous agents must be fully documented as part of the submission process of new protocols or amendments to the IACUC. The PI is responsible for providing a hazardous agent-specific plan to the VMC that emphasizes the management and safe animal practices to be utilized for the agent, including training for the VMU staff. Rodents in the (b)(6) rooms are housed in a ventilated rack or static micro-isolator cages with filter tops. All cages are changed in biological safety cabinets. All caging, bedding, food, water, protective garments and sanitizing equipment are autoclaved. LATs wear gowns, gloves, shoe and head covers, and N95 respirators when working with the animals. All personnel working in this area are trained and advised of risks associated with each agent.

How hazardous agents are contained:
All hazardous waste is autoclaved out of the facility and appropriately containerized in sealed red bags placed in a puncture proof red barrel with lids. The waste is then disposed through a licensed, certified medical waste contractor. Chemical agents are handled and contained according to guidelines provided by the SRSBS based upon review of the SDS and OSHA Chemical Hygiene Standards. Radioisotopes are contained according to policies established by the Radiation Safety Committee, depending upon the nature of the agent. Routine pickup of waste is scheduled according to the agent and volume. Each PI is responsible for assuring proper containment, handling, and storage of hazardous biologics, chemicals and radioisotopes.

Personal Protective Equipment:
Respirators and all needed disposable personal protective equipment (gowns, bonnets, gloves, shoe covers, etc.) are provided to VMU personnel and research personnel as needed.

Medical evaluation and preventive medicine for personnel:
The VA Employee OHSP includes a comprehensive program for individuals having animal contact in association with VA-sponsored activities. The requirements of the program are based upon the National Research Council (NRC) guidelines: an occupational health and Safety in the Care and Use of Research Animals (1997) and the Center for Disease Control and Prevention/National Institute of Health (CDC/NIH) guidelines, BMBL (5th Edition or current). The OHSP's goal is to prevent occupational injury and illness. The program consists of: Risk assessment, safety program, training, and education, rules and guidelines, medical monitoring and record keeping. In particular, we follow the Occupational Health and Safety and Personnel [Guide, pp, 14-18], Hazard Identification and Risk Assessment [see Chapter 2 in Occupational Health and Safety in the Care and Use of Research Animals, NRC 1997]

The SRSBS is responsible for the identification of biological and non-biological hazardous agents, oversight of chemical hazardous agents, and radiation safety. IBC is responsible for monitoring all activities, including risk assessment of recombinant DNA. Researchers are responsible for notifying SRSBS or the IBC if any hazardous agents are to be used in the conduct of research. Chemical hazard risks are determined by reviewing the SDS, experimental protocol, and specific agent. Biological hazard risks are evaluated according to the CDC/NIH BMBL. Proposals to use Biohazardous agents must be approved by the SRSBS. The Radiation Safety Officer evaluates radiation hazards for each isotope or procedure on a study specific basis. Guidelines published by the National and International Committees on Radiation Protection (ICRP and NCRP) are consulted. For all hazardous agents, the NRC Occupational Health and Safety in the Care and Use of Research Animals is further consulted. Animal-related risks are evaluated by the VMC and the SRSBS. The RSC conducts periodic visits to laboratories and facilities where hazardous agents may be present to determine compliance with institutional, city, state and federal regulations.

Reporting and treating bites, scratches, and injuries:
Bites and scratches are treated by the employee with the bite and wound kit provided in the VMU procedure room. Injuries, animal bites, scratches, needle sticks and cuts sustained in the VMU will be reported promptly to the employee's supervisor who ensures all required forms are completed. The employee is then referred to the Employee Health Physician. Employees must then enter the incident into the Automated Safety Incident Surveillance Tracking System (ASISTS).

Medical Monitoring: All research personnel are required to complete the Animal Contact Health Surveillance Questionnaire and acquire medical clearance before working with animals, their tissue or blood. Medical clearance is required annually. The VMU supervisor sends electronic notifications to all individuals 30 days prior to their medical clearance expiration. All individuals who use research animals are included in a health assessment program. The program shall include a comprehensive medical evaluation to ensure that the individual does not have medical problems that would create a health risk when working with animals. The health assessment provides baseline medical information to aid in the treatment of animal exposure or hazardous agent associated injury or illness. Annual (or more frequently, as indicated) medical monitoring includes all individuals who are in contact with research animals. The extent of the medical monitoring is based on the health hazard risk evaluation and the individual's medical history. Respirator fit test and training is conducted annually for individuals requiring respirators. Isolated one-time contact may not require participation in the medical monitoring program. Individuals involved in isolated one-time exposures are informed of potential dangers and medical precautions, including immunization recommendations. All individuals should have current tetanus immunization (within ten years of immunization or booster). The primary responsible party (PI, research director, student research coordinator, etc.) is responsible for assuring compliance with the notification requirements for these individuals.

Risk Assessment: According to our latest risk assessment, NMVAHCS is low risk having exposure to rodents or rabbits. We have no exposure to dogs, cats, ferrets, ruminants or primates. This risk assessment is revised as dictated by ongoing review.

F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed there and the average daily inventory of animals, by species, in each facility is provided in the attached Facility and Species Inventory table.

G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

New IACUC members are required to complete the www.CitiProgram.org "Essentials for IACUC Members" course. This course is repeated by all IACUC members every three years. In addition, new IACUC members receive a copy of the "Guide", current PHS Animal Welfare Assurance, VHA Handbook 1200.07, "Use of Animals in Research", and an integrated summary of the regulatory requirements applicable to VA Animal Research, "Nuts and Bolts of Regulatory Requirements for Use of Animals in Research." To support ongoing training for new and current members, we periodically discuss new policies and IACUC related scenarios (provided by the VA Office of the CVMO and other laboratory animal references) during our IACUC meetings. Members also have access to a small library in the VMU with publications, the AWAR, PHS policy, and Arena/OLAW IACUC Guidebook.

All personnel prior to working with live animals, their tissue or blood, are required to complete the "Working with the IACUC" course through the www.CitiProgram.org website. Other specific courses required depend upon species or procedures that they will use as described in protocols either approved or submitted for approval. The basic courses include:

- Species specific training (e.g. Working With Mice in Research Settings)
- Humane methods of animal maintenance and experimentation,
- Detecting, monitoring, and alleviating animal pain and distress,
- Research and testing methods that minimize the number of animals required to obtain valid results and minimize animal distress,
- Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility,
- Occupational health issues.

Completion requires a passing grade on the exams. Courses must be retaken every three years.

Depending on the complexity of the biotechnical procedures and level of competency described in the ACORP, the IACUC may require additional advanced education or hands-on training for

some individuals prior to beginning research. Hands-on biomethodology training is provided by the VMC, the VMU Supervisor, or other professionals with specified expertise. Some examples of advanced education may include:

- Handling, restraint, anesthesia and euthanasia of the specie(s) with which the person is working;
- Techniques of injection or blood collection as needed;
- Techniques of aseptic and survival surgery and post-surgical care if this is to be done; and
- Other techniques as determined by the IACUC.

Additional training for animal users may be required annually in order to update knowledge of animal care and use as required by the IACUC. All training is documented electronically and is retrievable by Research Administration.

IV. Institutional Program Evaluation and Accreditation

All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past 6 months and will be reevaluated by the IACUC at least once every 6 months according to PHS Policy IV.B.1.-2. Reports have been and will continue to be prepared according to PHS Policy IV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to the PHS Policy and the *Guide*. Any departures from the *Guide* will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC's evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

(1) This Institution is Category 1 — accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request.

V. Recordkeeping Requirements

A. This Institution will maintain for at least 3 years:
   1. A copy of this Assurance and any modifications made to it, as approved by the PHS
   2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations
   3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was granted or withheld
   4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, Andrew M. Welch.
   5. Records of accrediting body determinations

B. This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional 3 years after completion of the activity.

C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. Reporting Requirements

A. The Institutional reporting period is the calendar year (January 1 – December 31). The IACUC, through the Institutional Official, will submit an annual report to OLAW by January 31 of each year. The annual report will include:

1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked)
2. Any change in the description of the Institution's program for animal care and use as described in this Assurance
3. Any change in the IACUC membership
4. Notification of the dates that the IACUC conducted its semiannual evaluations of the Institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official, Andrew M. Welch.
5. Any minority views filed by members of the IACUC

If there are no changes to report, written notification that there are no changes will be provided

B. The IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
   1. Any serious or continuing noncompliance with the PHS Policy
   2. Any serious deviations from the provisions of the *Guide*
   3. Any suspension of an activity by the IACUC
      a. If the IACUC suspends an activity, the IACUC Chair or designee will report the finding directly to the IO within five (5) business days of the determination.
      b. If the IO suspends an activity it must be reported to the IACUC. The IO will then submit the formal report to the CVMO, OLAW, AAALAC and USDA (if a covered species). The Institution will also notify all applicable funding agencies.
      c. If the activity/protocol is reactivated following a majority vote of the IACUC, the entities listed in b. will be notified.

C. Reports filed under VI.A. and VI.B. above will include any minority views filed by members of the IACUC.

VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official

Name: Andrew M. Welch, MHA, FACHE

Title: Medical Center Director

Name of Institution: New Mexico VA Health Care System

Address:
1501 San Pedro Dr. S.E.
Albuquerque, NM 87108

Phone: 505-265-1711 x 2889 | Fax: 505-256-2855

E-mail: andrew.welch@va.gov

Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.

Signature: [signature] | Date: 7-20-17

B. PHS Approving Official *(to be completed by OLAW)*

Name/Title:
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6705 Rockledge Drive
RKL1, Suite 360, MSC 7982
Bethesda, MD USA 20892-7982 (FedEx Zip Code 20817)
Phone: +1 (301) 496-7163
Fax: +1 (301) 451-5672

Signature: (b)(6) | Date: August 1, 2017

Assurance Number: D16-00040 (A3073-01)

Effective Date: August 1, 2017 | Expiration Date: August 31, 2021

VIII. Membership of the IACUC

Date: April 14, 2017			
Name of Institution: VA – New Mexico VA Health Care System			
Assurance Number: D16-00040 (A3073-01)			
IACUC Chairperson			
Name*: (b)(6)			
Title*: Research Scientist		Degree/Credentials*: Ph.D.	
Address: 1501 San Pedro Dr. S.E. Albuquerque, NM 87108			
E-mail*: (b)(6) @va.gov			
Phone*: (b)(6)		Fax*: 505-256-2877	
IACUC Roster			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
(b)(6)	DVM, DACLAM	Veterinary Medical Consultant	Veterinarian
C13	PhD	Research Scientist	Scientist
C16		Retired Educator	Nonscientist/Nonaffiliated
C05		Wildlife Rehabilitator	Nonaffiliated Scientific
C01	LATG	VMU Supervisor	Member
C08	LAT	VMU Technician	Member
C10		Coordinator/Recorder	Non-voting

* This information is mandatory.

** Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this submission to OLAW. Sufficient information to determine that all appointees are appropriately qualified must be provided and the identity of each member must be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

*** List specific position titles for all members, including nonaffiliated (e.g., banker, teacher, volunteer fireman; not "community member" or "retired").

**** PHS Policy Membership Requirements:

Veterinarian	veterinarian with training or experience in laboratory animal science and medicine or in the use of the species at the institution, who has direct or delegated program authority and responsibility for activities involving animals at the institution.
Scientist	practicing scientist experienced in research involving animals.
Nonscientist	member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy).

Nonaffiliated individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution. This member is expected to represent general community interests in the proper care and use of animals and should not be a laboratory animal user. A consulting veterinarian may not be considered nonaffiliated.

IX. Other Key Contacts (optional)

If there are other individuals within the Institution who may be contacted regarding this Assurance, please provide information below.

Contact #1	
Name: (b)(6)	
Title: Chief, Research Administration	
Phone: (b)(6)	E-mail: (b)(6) @va.gov
Contact #2	
Name:	
Title:	
Phone:	E-mail:

X. Facility and Species Inventory

Date: April 17, 2017

Name of Institution: VA – New Mexico VA Health Care System

Assurance Number: D16-00040 (A3073-01)

Laboratory, Unit, or Building*	Gross Square Feet [*include service areas*]	Species Housed [*use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog*]	Approximate Average Daily Inventory
(b)(6)	7,500	Mouse	396
		Rat	7

*Institutions may identify animal areas (buildings/rooms) by a number or symbol in this submission to OLAW. However, the name and location must be provided to OLAW upon request.